E. Relationships With Providers

Part 422, subpart E of the M+C regulations focuses on requirements for relationships between M+C organizations and health care professionals with whom they contract to provide services to beneficiaries enrolled in an M+C plan. Many of these requirements stem from the rules regarding provider participation that are set forth in section 1852(j) of the Act. In our February 17, 1999 final rule, we addressed comments and made changes concerning several aspects of the provider participation requirements contained in subpart E, including the scope and applicability of the provider participation procedures. This final rule addresses comments on all other requirements in subpart E.

1. Provider Participation Procedures (§§422.202(a) and 422.204(c))

For the most part, we responded to comments on issues related to §§422.202(a) and 422.204(c) of the regulations in our February 17, 1999 final rule (64 FR 7975). In reviewing the comments on the interim final rule, however, we believe that additional clarification may be necessary on the applicability of the provider appeals procedures now set forth under §422.204(c).

Comment: Several commenters objected to language in the preamble to the June 26, 1998 interim final rule that implied that health care professionals should have access to a formal

appeals process when they viewed changes in an M+C organization's provider participation policies as having an adverse effect. The commenters pointed out that these policies should be subject to the consultation rules set forth under §422.204(b), but did not believe that changes in these policies warranted a formal appeals process.

Response: As discussed in the February 1999 rule, the appeals procedures set forth under existing §422.204(c) apply only in cases of adverse participation decisions, that is, when an M+C organization suspends or terminates a physician's contract with the organization. We believe this policy is consistent with the intent of section 1852(j)(1) of the Act, which provides for a process for appealing "adverse decisions" relating to the "participation of physicians" under a plan. We did not intend to imply that a physician has a right to a formal hearing to appeal a participation policy adopted by the M+C organization, although we would expect physicians to have input on those polices through the consultation process required under §422.202(b). Clearly, however, an M+C organization ultimately is legally entitled to adopt the policies necessary to govern its operations, as approved by its board of directors, provided they are consistent with applicable Federal requirements. Please note that as part of a minor restructuring of the M+C provider participation provisions, and to help clarify that the appeals procedures apply

only for adverse participation decisions, we are redesignating the provider appeals procedures from §422.204(c) to new §422.202(d).

Comment: Two commenters objected to the requirement in existing §422.204(c)(3) that an M+C organization must notify the appropriate licensure or disciplinary bodies when it suspends or terminates a contract because of deficiencies in the quality of care. These commenters suggested that we leave State reporting requirements to the States. Another commenter recommended that the appeals hearing panels (under §422.202(c)(2)) be required to include physicians that did not contract with the M+C organization as a means of ensuring the "independence" of the panel's review.

Response: Existing statutes and regulations consistently establish the need for cooperation between Federal and State authorities in their administration of the Medicare program. A primary example is the requirement under section 1855(a)(1) of the Act that an M+C organization generally must be licensed under State law in order to qualify for participation in the M+C program. Thus, we believe it is wholly appropriate to require in Federal regulations that the suspension or termination of a physician's contract with an M+C organization be reported to State licensing and disciplinary bodies.

With regard to the membership of appeals panels, an M+C organization is free to enlist non-contracting physicians on these panels if it chooses to do so. However, section 1852(j)(1)(C) of the Act refers to an appeals process "within the organization," and we do not believe it would be reasonable to require the participation of non-contracting physicians.

Comment: A commenter pointed out that at least one State has laws exempting an organization from the State's requirements for provider notification and review procedures in cases of imminent harm to a patient, determination of fraud, or final disciplinary action by a State licensing board. The commenter asked whether the notification and appeals provisions of subpart E would preclude exemption in these situations.

Response: As discussed in further detail below, section 1856(b)(3)(B) of the Act specifies that State "requirements relating to inclusion or treatment of providers" are superseded by the analogous Federal standards. Thus, State reporting exceptions to the M+C notification and appeals procedures are precluded under the existing M+C regulations. However, we do not believe that the general notice requirement under existing §422.204(c)(1) and (3), which do not include specific time frames for notification, should present a conflict with the State law mentioned by the commenter. We note that 60-day time frame for termination notifications under §422.204(c)(4) applies only for

terminations “without cause,” rather than in situations addressed by the law in question.

2. Consultation Requirements (§422.202(b))

In accordance with section 1852(j)(2) of the Act, §422.202(b) specifies that an M+C organization must consult with physicians participating in its M+C plans regarding the organization's medical policies, quality assurance programs, and medical management procedures. Under the regulations set forth in our June 26, 1998 interim final rule, these provisions were applied to other health care professionals as well as physicians. However, in response to comments on the interim rule, we revised this section in our February 1999 final rule to limit the applicability of these requirements to physicians. We also received a number of comments on other aspects of the consultation provisions, which are discussed below.

Comment: Commenters generally supported the objectives of the consultation requirements contained in §422.202(b). However, several commenters representing physician groups suggested that the regulations should be expanded to establish a specific methodology for obtaining consultative input. For example, one commenter advocated requiring the establishment of a medical committee structure broken down into separate subcommittees focusing on various aspects of medical management policy (for

example, professional relations, credentialing, quality improvement, etc.).

Other commenters representing M+C organizations asked for confirmation that the use of physician committees to obtain consultation was an acceptable means of satisfying the consultation requirements. Two M+C organizations suggested that we define "consultation" as "soliciting and considering advice from participating professionals through committees established by the M+C organization." Another commenter noted that local medical review procedures (LMRP) should be part of the consultation process, and could in some instances substitute for the consultative process. One commenter indicated that the consultative requirements could be read to require consultation with hundreds of individual physicians and expressed concern that the consultative requirements would interfere with an individual physician's judgement in treating patients.

Response: We agree that the most appropriate method for an M+C organization to consult with its contracting physicians is likely to be through the establishment of a committee structure. Rather than limit organizational flexibility by establishing a single model for consultation, however, we are revising §422.202(b) to state that an M+C organization must "establish a formal mechanism" for consulting with the physicians who provide services under plans offered by the organization. As we monitor

the types of consultative arrangements implemented by M+C organizations, we will consider whether more specific regulatory guidance is necessary.

Similarly, although we agree with the definition of consultation offered by the commenters, we believe that the term is sufficiently self-explanatory and that inserting a formal definition of the term into the regulations is unnecessary. We also agree that M+C organizations should take local medical review policies into consideration in establishing and updating their medical review policies. However, we believe that the regulations need not include that degree of specificity concerning the evidence-based guidelines an M+C organization must consider in adopting practice guidelines. We will consider adding such policies to the list of guidelines now described in the QISMC standards on this subject (QISMC Guideline 3.4.1.1).

Finally, we do not agree that the consultation requirement infringes on the ability of an individual physician's judgement in the practice of medicine. As their name implies, practice "guidelines" are intended for general application rather than as procedures to be followed in every case independent of physician judgment.

3. Treatment of Subcontracted Networks (§422.202(c))

Under §422.202(c), an M+C organization that uses subcontracted physician groups or other networks of health care

professionals must provide M+C participation procedures that apply equally to these subcontracting groups.

Comment: Many commenters raised questions concerning the meaning and implications of the requirement under §422.202(c), which states that when an M+C organization operates an M+C plan through subcontracted physician groups or other subcontracted networks, it must ensure that "the participation procedures in this section apply equally to physicians and other health care professionals within those subcontracted groups." (Note that this provision was amended in our February 1999 final rule to limit its applicability to physicians.) Although some commenters supported this requirement as written, others were concerned that the requirement was too broad in scope. Several commenters suggested that we clarify that an M+C organization can comply with this provision by requiring subcontracting networks to have their own procedures for consultation and for participation appeals. They believe that it would be imposing "unreasonable downstream responsibilities" to require that the subcontractor's consultation and appeals procedures establish participation rights equivalent to those required under §422.202. Other commenters recommended that we require the subcontracts to include the same specific appeals procedures as required at the M+C organization level. Finally, several commenters asked whether appeal rights extend to all physicians in a terminated

group practice or to individual physicians. They recommended that the subcontracting group practice exercise appeal rights on behalf of its employees.

Response: M+C organizations are contractually obligated to meet all requirements contained in the M+C regulations. They may meet these requirements either by directly providing the requisite health or administrative services or by entering into contracts for the provision of these services. Although we recognize the need for further clarification of how the provider participation rules and other provisions of the M+C requirements apply to subcontracting entities, the presence of a subcontract does not alter the underlying substance of those requirements. Note that §422.502(i) of the M+C regulations contains a great deal of general information regarding the delegation of responsibility under subcontracts as well as some specific requirements (for example, with respect to provider credentialing). Please see section II.K of this preamble for a further discussion of many related issues. In addition, readers may wish to consult OPL #77, released on December 8, 1998, which offers extensive guidance in this regard (available through the HCFA website at www.hcfa.gov).

As spelled out under §422.502(i), under any type of subcontracting arrangement, the M+C organization retains ultimate responsibility for ensuring that its subcontractors achieve full

compliance with all terms and conditions of the organization's contract with us. This includes ensuring that activities performed by its subcontractors are consistent and comply with the M+C organization's contractual obligations. For activities that are delegated to contractors (such as provider appeals), the contract must specify that the subcontractor must comply with all Medicare laws, regulations, and instructions. Thus, a physician who is employed by a group practice that contracts with an M+C organization would have the same fundamental consultation and appeal rights as a physician who contracts directly with the M+C organization. Whether that physician exercises those rights at the subcontractor level, or directly through the M+C organization, would be left to the discretion of the M+C organization and its subcontractors. For example, an M+C organization could enter into a contract with a physician group under which all individual appeals of adverse participation decisions were adjudicated at the subcontractor level. However, the subcontractor's appeals process would need to meet the requirements established under redesignated §422.202(d), as discussed above: all procedural rights established there would apply equally for the subcontracting physicians. For situations in which a subcontract with an entire group practice was terminated by an M+C organization, we would expect that the

appeal rights would fall to the subcontracting group practice to exercise on its physicians' behalf.

Similarly, with respect to the consultation requirements, we can envision various ways in which the requirements could be met under subcontracting arrangements, such as through direct representation for the subcontractor's providers on M+C organization committees, or through committees convened by the subcontractor, with its consultative input channeled to the M+C organization. In either case, though, the underlying requirement must be met that practice and utilization management guidelines be developed in consultation with contracting physicians.

In general, our policy to date has been to afford extensive flexibility to M+C organizations in meeting subcontracting requirements. In 1999, for example, we required risk contractors that became M+C organizations to submit a plan demonstrating how they would work toward executing new or revised provider or administrative service contracts, with full compliance required by January 1, 2000. Again, for further information on the ways in which an organization can demonstrate compliance with provider contracting requirements, please see OPL 77.

4. Provider Antidiscrimination (§§422.100(j), 422.204(b), new 422.205)

Sections 422.100(j) and 422.204(b) both relate to the provision set forth in section 1852(b)(2) of the Act that

precludes M+C organizations from discriminating against providers based on their licensure or certification. Section 422.204(b), for the most part, simply incorporates the statutory prohibitions on discrimination based on provider licensure or certification, but also provides that these prohibitions do not preclude the "use of different reimbursement amounts for different specialties." Section 422.100(j) states that if more than one type of practitioner is qualified to furnish a particular service, the M+C organization may select the type of practitioner to be used.

Comment: Numerous commenters addressed the provider antidiscrimination provisions set forth at §§422.100(j) and 422.204(b). Commenters generally believed that additional guidance beyond that offered in the June 1998 interim final rule was necessary to clarify our interpretation of the antidiscrimination provisions of the statute (section 1852(b)(2) of the Act). Commenters differed in their views on how these provisions should be interpreted and implemented, however.

In general, commenters representing M+C organizations supported the inclusion of the choice-of-practitioners provision (§422.100(j)); they believe that this provision establishes that M+C organizations are not required to adopt an "any willing provider" policy, but rather have the flexibility to choose the practitioners that participate in an organization's provider

network. In contrast, commenters representing physicians and other health care professionals believe that the choice-of-practitioners provision is unnecessary and confusing; they see the provision as undermining the antidiscrimination provisions of the statute and the M+C regulations. These commenters particularly objected to the wording in §422.100(j) that allows an M+C organization to select the "type of practitioner" to be used. These commenters offered various recommendations, including: (1) delete the provision in its entirety; (2) add a requirement that an M+C organization employ a "representative range of providers" (comparable with the available range of providers under original Medicare); (3) amend the provision so that it would focus on the availability of all Medicare-covered "benefits" (many of which can be furnished only by qualified practitioners), rather than "services".

Commenters displayed similar perspectives with regard to the antidiscrimination prohibitions set forth under §422.204(b). As noted above, the only portion of this section that is not taken directly from the statute is the provision under existing §422.204(b)(2)(ii) that indicates that an M+C organization is not precluded from use of different reimbursement amounts for different specialties. Commenters representing M+C organizations generally supported the addition of this language, although one commenter believed that it unnecessarily restricted an M+C

organization's ability to negotiate with physicians or other practitioners. This commenter stated that the regulations do not give an organization sufficient leeway to take into consideration the reputation, volume, or experience of a practitioner, or alternative payment methods, in establishing compensation.

Other commenters representing various types of physicians and other health care professionals objected to this provision because they believe that it confers too much authority on M+C organizations. They argued that permitting an M+C organization to pay different amounts for different specialties was inconsistent with legislative intent. They also contended that this language was inconsistent with the Supreme Court's decision in Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667 (1986), which they characterized as requiring that Medicare "reimburse similar services in an equal manner regardless of who performs the service." These commenters believed that we should require that payment rates be tied to the services provided, as under the fee schedules used in original Medicare. One commenter suggested that we revise §422.204(b)(2)(ii) to clarify that payment differences are permissible only if they "result from competition or other legitimate factors," rather than differences based solely on licensure or certification.

Response: The statutory antidiscrimination provision is intended to ensure that health care providers are not arbitrarily

excluded from participation under a managed care plan’s provider network solely on the basis of their license or certification. We recognize that the existing regulations, which refer to this prohibition on discrimination in both §§422.100(j) and 422.204(b), have created the potential for confusion.

To assist in clarifying the relevant requirements, we believe it is appropriate to consolidate the regulations concerning antidiscrimination and choice of providers into a new, separate §422.205, Provider antidiscrimination. This section will begin with the general rule prohibiting discrimination based solely on licensure or certification, consistent with the law. We then will specify that in choosing its practitioners, an M+C organization must ensure that all Medicare-covered services must be available to a plan's enrollees. We are also incorporating under §422.205(a) a revised version of the existing provision regarding choice of practitioners that eliminates any reference to "type of practitioners." Thus, the general rule will continue to permit M+C organizations the flexibility to choose their practitioners, consistent with the statute's antidiscrimination constraints, which are set forth under §422.205(b). At the same time, this provision will emphasize the mandatory availability of all Medicare-covered services (such as physical therapy or manual manipulation of the spine to correct a subluxation).

Finally, we are adding at, §422.205, a requirement that when an M+C organization declines to include a given provider or group of providers in its network, it must notify the provider(s) of the reason for its decision. Although this provision does not impart any appeal rights, we believe it is both a reasonable business practice and a means of ensuring that such decisions are subject to our monitoring efforts.

Our goal in implementing these changes is to strike a balance between our responsibility to ensure that M+C organizations are employing all the types of health care professionals needed to ensure that required Medicare-covered services are available to their enrollees, and our aversion to limiting organizations' flexibility in providing these services. Over the next few years, we intend to closely monitor organization compliance with the antidiscrimination provisions, including examining encounter data as it becomes available and tracking organizational participation decisions, to determine the degree to which all Medicare-covered services are made available under different plans.

We believe that the statute is not intended to preclude an M+C organization from negotiating appropriate, market-based, payment rates with its providers. It is quite possible, for example, that the "market rate" that must be paid to get a particular type of specialist to participate in an M+C

organization’s network may be higher or lower than that dictated by the market with respect to another type of practitioner. Section 1852(b)(2) of the Act expressly provides that its antidiscrimination rule "shall not be construed to prohibit a plan from. . . measure[s] designed to. . .control costs. . . ." Paying no more than the market rate for a given provider is clearly a component of cost control. We believe that establishing requirements concerning the comparative rates M+C organizations pay for contracting provider services would be inconsistent with the overall design of the M+C program, under which we pay a fixed amount to ensure that Medicare beneficiaries receive the services to which they are entitled, but M+C organizations have wide discretion in managing enrollee care and establishing provider networks. Inherent to this design is the premise that payment rates should be established through negotiated contracts rather than micro-managed by the Federal government. Thus, new §422.205(b) specifies that an organization may use different reimbursement amounts for different specialties, or different practitioners within the same specialty.

Further, we do not agree with the commenter that the payment rules established under original Medicare's fee schedules necessarily represent the appropriate model for payment under the M+C program, or that it would be appropriate or feasible to

establish a requirement that an M+C organization's provider network reflect the identical mix of providers participating in Medicare generally. Beneficiaries have the option of returning to original Medicare if they place a premium on being able to receive services from any provider they wish, or are not satisfied with being limited to a defined network established by an M+C organization.

In addition to addressing measures designed to control costs, section 1852(b)(2) of the Act also makes clear that the antidiscrimination rule therein shall not be construed to prevent an M+C organization from taking measures to "maintain quality" of services. For example, we would not want to preclude higher payments to providers for demonstrating quality improvement, or preclude an M+C organization from imposing quality-related requirements, such as using only board-certified physicians.

Finally, section 1852(b)(2) of the Act makes clear that its antidiscrimination provision "shall not be construed to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan’s enrollees." If an M+C organization can provide all physicians’ services through a doctor of medicine, it may not "need" to contract with another practitioner who can provide only a discrete subset of physicians’ services (such as a podiatrist or a chiropractor who under section 1861(r) of the Act are considered physicians under Medicare only for

specified purposes). As long as all Medicare-covered services are available in the plan, there may be no "need" to assume the additional administrative costs of contracting with another practitioner when an existing contractor is able to perform the services the additional practitioner would be providing. This would not constitute discrimination based "solely" on the basis of license or certification, but rather, not contracting with practitioners not "needed" to provide the full Medicare range of benefits.

With respect to the choice-of-practitioners provision, this right has always been inherent in the managed care model of health care delivery. While a practitioner is not to be discriminated against solely due to his or her license, we believe that M+C organizations must have the flexibility to deliver services through the most cost-effective practitioner who is qualified to perform the service in question. Again, this is a "cost control" measure authorized under the last sentence in section 1852(b)(2) of the Act.

We do not understand the commenter's reference to the Supreme Court's Michigan Academy decision, since this decision did not involve a ruling on the merits of any reimbursement issue. Rather, the issue in Michigan Academy was whether certain types of claims were subject to judicial review. Even if the decision did hold what the commenter suggested, rules that apply to

payments under original fee-for-service Medicare do not apply to payments by M+C organizations to contracting providers.

Comment: Commenters asked how we intended to enforce the antidiscrimination requirements, noting that strong enforcement was particularly necessary in view of the specific preemption of State laws dealing with the inclusion of providers. Several commenters asked how a provider would pursue an antidiscrimination claim, and they urged us to establish an administrative review process for investigating allegations of discrimination based on licensure or certification. To facilitate the reviews, these commenters suggested that the regulations require that notices of adverse participation decisions include a statement of the reasons for the determination.

Response: Although we do not intend to establish a separate administrative review process for investigating allegations of discrimination against providers, we intend to place a strong emphasis on verifying that M+C organizations are in compliance with the antidiscrimination provisions. This will occur both through our scheduled monitoring activities and under our authority to conduct complaint investigations when we believe there is credible evidence of violations.

In addition, as noted above, §422.205 will now incorporate the requirement that an M+C organization must state in writing

its reasons for declining to include any given provider or group of providers in its provider network. This should enhance our ability to identify violations of the antidiscrimination requirements, for example, by detecting situations in which organizations exhibit a pattern of repeated refusal to contract with certain types of practitioners. If a prospective provider has evidence of discrimination on the basis of licensure, the appropriate avenue to raise this concern is the HCFA regional office in the relevant area.

Comment: One commenter expressed concern that without further clarification, the choice-of-practitioners provision at existing §422.100 could be construed as giving an M+C organization complete and final authority over an enrollee's choice of health care provider. The commenter recommended that we clarify that an enrollee may appeal a plan's decision not to allow access to a specialist, or a specific provider, that the enrollee believes is necessary to furnish adequate services.

Response: The regulations concerning choice of practitioners are not intended to limit in any way the appeal and grievance rights of enrollees under subpart M of the M+C regulations. If an enrollee is denied access to a specialist, the enrollee clearly has the right to a timely organization determination and, if necessary, a reconsideration of this determination. Situations involving whether a specific provider is necessary are

more likely to be subject to either the organization's grievance procedures or possibly to external review by a PRO if quality issues are involved.

5. Provider Credentialing (§422.204(a))

Ensuring that providers have the proper credentials for the services they are providing is a key component of an overall "ongoing quality assurance program for health care services," as required under section 1852(e)(1) of the Act. Section 422.204(a) accordingly sets forth basic requirements that an M+C organization must follow with respect to the credentialing and recredentialing of the providers and suppliers with whom it enters into participation agreements. The M+C organization must ensure that providers and suppliers meet applicable State and Federal requirements. Basic benefits must be provided through, or payments must be made to, providers that meet applicable requirements of title XVIII and part A of title XI of the Act. Also, in the case of providers meeting the definition of "provider of services" in section 1861(u) of the Act, §422.204(a)(3)(i) specifies that basic benefits may only be provided through such providers if they have a provider agreement with us permitting them to provide services under original Medicare. An M+C organization may not employ or contract with providers excluded from participation in Medicare.

Comment: Although commenters generally supported the flexibility built into the M+C credentialing provisions, several commenters suggested that the credentialing standards used by the NCQA be incorporated into the M+C regulations because these commenters believe that they are clear and adequate to protect M+C beneficiaries. Several commenters contended that many of the M+C credentialing standards were somewhat vague; one commenter identified as particularly unclear the requirement under §422.204(a)(2)(iii) to establish a process to "receive advice" from contracting health care professionals with respect to credentialing criteria. Another commenter asked if, in general, an M+C organization that complies with NCQA credentialing standards would also be in compliance with the M+C requirements. The commenter asked for confirmation that, like under the NCQA standards, the following categories of practitioners are not subject to the credentialing requirements: 1) hospital-based practitioners that provide care for an M+C organization's enrollees only as a result of members being directed to the hospital, and 2) practitioners who provide care only under the direct supervision of a contracting physician. Another commenter asked for additional clarity as to what types of practitioners must be credentialed and suggested following NCQA standards. One commenter argued that the credentialing provisions should

include substantive criteria governing which physicians will be credentialed in the network, which excluded, and on what grounds.

Response: In view of these comments, we have reexamined the existing credentialing provisions and are making several changes. First, as discussed above, we have removed both the antidiscrimination and the provider appeals provisions from §422.204. Section 422.204 will now be entitled "Provider selection and credentialing" and will include a new §422.204(a) to establish the general rule that an organization must have written policies and procedures for the selection and evaluation of providers. These policies and procedures must conform with the existing credentialing requirements, which will be redesignated as §422.204(b), as well as the antidiscrimination procedures now contained under new §422.205. These changes do not impose new substantive requirements on M+C organizations, but we believe they constitute both a necessary reorganization of the existing requirements, and a means of clarifying in the regulations the inherent purpose of the credentialing rules--the need for a systematic approach to provider selection. We note that both the NCQA standards and our QISMC standards already incorporate the underlying concept that an organization's credentialing requirements are an integral component of its provider selection policies.

This change in no way obviates our awareness that an organization's selection criteria, and thus its credentialing policies and procedures, should be tailored to take into account the individual characteristics of each M+C organization. The process of provider selection also should be integrated with the process of establishing and maintaining an adequate provider network to assure enrollee access to plan services. Thus, we do not intend to add to the regulations greater specificity concerning the procedures an M+C organization must follow for credentialing and recredentialing purposes, or establish detailed criteria as to what constitute adequate credentials. Instead, the regulations will continue to require that M+C organizations follow a "documented process" for these activities that meets the relatively flexible existing standards.

With respect to the question about whether meeting NCQA standards would constitute compliance with M+C requirements, we are currently evaluating this question in the context of the "deeming" provisions discussed in section II.D above. If we find that NCQA, or any other private accreditation organization, applies and enforces standards that are at least as stringent as those set forth in §422.204, then satisfying NCQA standards would constitute compliance with M+C requirements. Until we make such a determination, however, meeting NCQA credentialing standards does not necessarily achieve compliance with the M+C

requirements. We note that we agree with NCQA that credentialing is not required for health care professionals who are permitted to furnish services only under the direct supervision of a physician or other provider, or for hospital-based health care professionals (such as an emergency room physician, anesthesiologist, or certified registered nurse anesthetist (CRNA)) who provide services to enrollees only incident to hospital services. (This exception does not apply if the practitioner contracts independently with the M+C organization or is promoted by the organization as being part of its provider network.)

Finally, we agree that the requirement that an M+C organization's process include "receiving advice" from contracting health care professionals could be misconstrued. We are changing this requirement to indicate that the organization must have a process for consulting with its contracting health care professionals on its credentialing and recredentialing criteria.

Comment: Several commenters suggested technical changes to the regulations in subpart E. For example, one commenter recommended that the credentialing provisions consistently refer to suppliers as well as providers, noting that the subpart E basis and scope section (§422.200) explicitly mentions both providers and suppliers, while §422.204(a)(3)(i) only refers to

the furnishing of basic benefits through "providers." The commenter also recommended that pharmacies be considered as providers. Another commenter suggested that we add "or certification" to the licensure verification requirement under §422.204(a)(2)(i), and asked whether Joint Commission on Accreditation of Health Care Organizations/Community Health Accreditation Program or Medicaid certification of an HHA was sufficient to meet the provider credentialing requirements, as has been the case in the past for Medicare managed care.

Response: The definition of providers that applies for purposes of the M+C program is found at §422.2 and includes both entities that would be considered providers and suppliers for other Medicare purposes. However, to avoid any possible confusion, we are adopting the commenter's recommendation that suppliers be explicitly mentioned under existing §422.204(a)(3)(i) (now redesignated as §422.204(b)(3)(i), as discussed above). Pharmacies, thus, are considered "providers" for purposes of the M+C program. We are also amending the regulations to indicate that initial credentialing should include verification of licensure or certification.

Existing §422.204(a)(3)(i) requires that in the case of providers of services that meet the original Medicare definition of "providers" under section 1861(u) of the Act (such as HHAs or SNFs), that provider must have a provider agreement with us in

order to be permitted to furnish basic benefits under an M+C plan. Under this requirement, neither accreditation nor approval under the Medicaid program is necessarily sufficient to enable an HHA to furnish services under an M+C plan, unless the HHA is Medicare-certified. The objective of this policy is to ensure that M+C enrollees are guaranteed services of a quality level at least equal to that available to other Medicare beneficiaries. We continue to believe that the existence of a provider agreement with us is the best way to ensure that HHAs providing services to M+C enrollees meet uniform standards in all States and are subject to Federal enforcement authority. Thus, we believe it would be inappropriate to create an exception for HHAs to the general rule that "providers of services" as defined under section 1861(u) of the Act must have a provider agreement that permits them to furnish services under original Medicare.

Comment: One commenter stated that the credentialing requirements appeared to require individual credentialing for physicians in group practices. The commenter believed that this requirement is too inflexible and could delay a physician's inclusion in a network. Instead, the commenter recommended that an M+C organization have the option of credentialing a group practice as network participants, and then transferring the obligation to credential new members of the practice to the practice itself.

Response: When an M+C organization contracts with a group practice, it has an obligation to ensure that all members of that practice meet its credentialing standards. Consistent with the discussion of subcontracting rules above (and with the subcontracting requirements of §422.502(i)(4)), subsequent credentialing may be carried out either by the M+C organization itself or be delegated to the subcontracting organization (that is, the group practice). If delegated, however, the M+C organization must review and approve the credentialing process, and audit the process on an ongoing basis.

Comment: One commenter objected to several aspects of the credentialing requirements, and urged that they be modified to take into account the varying characteristics of M+C networks such as PPOs. The commenter recommended that the requirement for site visits be eliminated for PPOs, and that the requirement for recredentialing every 2 years be modified in favor of permitting M+C organizations to determine when recredentialing was appropriate depending upon the size and stability of the provider network.

Response: Under the existing regulations, site visits are required "as appropriate" for initial credentialing; thus, sufficient flexibility already exists in this regard. We believe that recredentialing every 2 years is a reasonable time frame and note that it coincides with NCQA standards. We believe it would

be inappropriate for each M+C organization to substitute its judgment for a national standard as to when it should recredential its practitioners. If the provider network is small and stable, the administrative burden associated with the recredentialing process should be relatively small.

Comment: One commenter noted that the prohibition on entering into contracts with providers that are excluded from participation in the Medicare program (under existing §422.204(a)(3)(ii)) is impossible to implement unless the HCFA website includes a Social Security number (SSN).

Response: As noted in the interim final rule, M+C organizations are expected to consult the Office of Inspector General's (OIG) website (www.dhhs.gov/progorg/oig) to access the list of providers that are excluded from participation in the Medicare program. For privacy reasons, this listing does not include SSNs. However, we also maintain an internal excluded provider list (HCFA Publication 69) that includes unique identifying information for the providers in question. This publication generally is available to all of our contractors, including M+C organizations. We suggest that any M+C organization that needs this information contact either its regional or central office plan manager, or HCFA's Office of Issuances to obtain the latest version of Publication 69.

6. Prohibition on Interference with Health Care Professionals' Communication with Enrollees (§422.206)

Consistent with section 1852(j)(3)(A) of the Act, §422.206(a) prohibits an M+C organization from interfering with the advice of a health care professional to an enrollee who is his or her patient. Thus the health professional may act within his or her scope of practice in advising the enrollee about his or her health status, all relevant medical or treatment options available regardless of whether care or treatment is provided under the plan. Section 422.206(b) incorporates the requirements of section 1852(j)(3)(B) of the Act. The regulations state that the prohibition against interference with the content of advice a health care provider has given to enrollees regarding medical treatment should not be construed as requiring counseling by a professional, if the M+C organization objects, based on moral or religious grounds, and fulfills certain notification requirements to prospective and current enrollees. The regulations incorporate the notification process and time frames included in the law and clarify that the plan must also notify us at the time of application and within 10 days of submitting its ACR proposal. We received 12 comments addressing the provisions set forth under §422.206.

Comment: The majority of the commenters simply expressed their support for this provision, which has been referred to as

the "anti-gag rule." One commenter asserted that an M+C organization should not be forced to provide care that is not medically effective, approved by the Food and Drug Administration (FDA), or covered under the enrollee's plan. A commenter also suggested that M+C organizations be prohibited from requiring health care professionals to sign "gag rule" clauses that interfere with full disclosure of all treatment options, regardless of whether theses options are covered under a plan. Another commenter noted that §422.206(d) states that an M+C organization is subject to intermediate sanctions for violations of these provisions, and recommended that the regulations also specify that we will not renew the contract of an M+C organization that substantially violates the provisions in §422.206.

Response: As indicated in the June 1998 interim final rule, a health care professional's freedom to inform an enrollee about available treatment options in no way implies that all of the possible treatment options (for example, experimental or noncovered alternatives) are covered under the enrollee's M+C plan. In other words, the prohibition on interference with provider-enrollee communications does not affect the M+C benefit and coverage requirements. Clearly, these rules prohibit an M+C organization from requiring health care professionals to sign a "gag rule" clause, such as that mentioned by the commenter.

Finally, we note that under §422.506(b)(1)(iv) of the M+C contracting regulations, an M+C organization that commits any acts that can support the imposition of intermediate sanctions is also subject to nonrenewal of its contract.

Comment: One commenter representing health insurance agents recommended that the regulations include a prohibition on physicians "advising seniors on M+C plans." The commenter asserted that only individuals with health insurance licenses should be permitted to proffer such advice.

Response: Although we recognize that there are situations where it would be inappropriate for physicians or other health care professionals to "steer" beneficiaries to particular health care plans, we do not believe that prohibiting patients from seeking advice from physicians regarding insurance coverage choices is either necessary or practical. For example, a physician should be able to disclose to a patient the M+C plans in which he or she is a network provider. (For additional discussion of this issue, please see the portion of section II.B of this preamble that discusses M+C marketing requirements at §422.80.)

Comment: Two commenters recommended that we either delete or clarify the requirement in §422.206(a)(2) that health care professionals provide information regarding treatment options in a "culturally competent manner."

Response: We recognize that the term "culturally competent" can be subject to various interpretations, as discussed in detail above in section II.C of this preamble concerning M+C access requirements. For the purposes of this provision, our intent is that M+C organizations establish and maintain effective communication with enrollees, including informing them of treatment options in a language they can understand.

Comment: Two commenters raised concerns related to the conscience protection exceptions set forth in §422.206(b). One commenter strongly supported the provisions, but recommended that the final rule clarify that: (1) nothing in the conscience protection provisions be construed as limiting the range of services to which Medicare beneficiaries are entitled; (2) an enrollee may terminate enrollment and choose another M+C plan if he or she receives notification under this section that an M+C organization will not cover or pay for a particular counseling or referral service; and (3) like other disclosure requirements, notifications required under §422.206(b)(2) must be provided in a clear, accurate, and standardized form, consistent with the special needs of individual enrollees.

Another commenter asserted that there was a potential conflict between the conscience protection provisions and the information disclosure rules in §422.111 and recommended that we establish an exception to the advance disclosure rules for "duly

adopted religious policies." The commenter noted that the conference agreement to the BBA indicates the Congress' intent that the Secretary not "impose burdensome regulatory, legal, or stylistic requirements with respect to this notice requirement." (House Report, 105-217, pg. 607.)

Response: As the commenter points out, the conscience protection provisions in no way diminish or otherwise affect the range of benefits or services to which Medicare beneficiaries are entitled. As discussed in section II.C above, the conscience protection in section 1852(j)(3)(B) of the Act affects only obligations under section 1852(j)(3)(A), not obligations that arise elsewhere in the statute, such as the obligation under section 1852(a)(1) to provide all Medicare-covered services available in the area served by the M+C plan. To the extent that the operation of the right to advice and counseling under section 1852(j)(3)(A) would obligate an M+C organization to cover counseling or referral services that it would not otherwise be obligated to cover, section 1852(j)(3)(B) allows the organization to decline to provide such service on conscience grounds if notice is provided to beneficiaries. However, if the service is one that the organization is obligated to provide independent of section 1852(j)(3)(A), it could not be affected by a provision that by its own terms affects only the way that "[s]ubparagraph (A) [of section 1852(j)(3)] shall. . . be construed." It in no

way affects obligations that arise elsewhere in the statute. Therefore, an M+C organization could not rely upon section 1852(j)(3)(B) or §422.206(b) in an attempt to avoid coverage of services that it is obligated under section 1852(a)(1) to cover. We note, however, that in the case of abortion-related services, the Congress has provided M+C organizations with certain conscience protections independent of that in section 1852(j)(3)(B) of the Act. Specifically, under section 216 of the fiscal year 1999 appropriations legislation (Pub. L. 105-277), we are prohibited from denying an M+C contract to an entity on the grounds that it refuses on conscience grounds to cover abortions. Beneficiaries, nevertheless, retain the right to such services, and Medicare must cover them. We are required, however, to make appropriate adjustments to such an entity's M+C capitation payments to cover our costs in providing Medicare-covered abortion services outside the M+C contract.

We agree that the disclosure provisions under §422.206(b) should be read consistently with other disclosure provisions in the regulations, and thus M+C organizations must take into account the special needs of individuals who are blind, disabled, or cannot read or understand English. The notification requirements set forth in §422.206(b)(2) are not intended to result in an M+C organization being put in the position of being required to furnish counseling or referral services that violate

a duly adopted religious policy. Experience indicates that neither changes in Medicare coverage policies nor in "duly adopted" religious policies take place so quickly as to preclude an M+C organization from providing advance notice to us, and then to enrollees, concerning service restrictions based on such policy changes. Thus, we believe that only very rarely, if ever, would a conflict exist between the advance disclosure requirement of §422.111(d) and the provision that permits an organization to implement a conscience exception, provided that it notifies its enrollees of such changes within 90 days after adopting the change. Consequently, we do not view the advance disclosure procedure as a burdensome requirement.

7. Physician Incentive Plans (§§422.208 and 422.210)

Sections 422.208 and 422.210 outline the limitations and disclosure rules for physician incentive plans. Specifically, §422.208 applies to an M+C organization and any of its subcontracting arrangements that use a physician incentive plan in their payment arrangements with individual physicians or physician groups. With the exception of the deletion of a requirement that information on expenditures of capitation payments be reported to us, the provisions in these sections are essentially the same as those that previously applied to Medicare risk plans under §417.479. We received several comments regarding physician incentive rules.

Comment: A commenter contended that the 25 percent threshold for substantial financial risk is too high, noting that we have acknowledged that this represents an outlier approach, and that risk arrangements in the range of 10 to 15 percent are far more prevalent than those in excess of 25 percent. This commenter argued that the 25 percent threshold may render the rule irrelevant as applied to the majority of M+C organizations. In addition, the commenter is concerned that because the exemption level is set so high, the effect of the exemption may be to discriminate against plans that are in the process of growth, thus giving the larger plans a competitive advantage.

Response: As we indicated in the preamble to the physician incentive plan regulation published on March 27, 1996 (61 FR 13430), we believe that the 25 percent risk threshold is appropriate because of the outlier methodology that we used. The median withholds are in the 10 to 20 percent range. This was the best methodology in formulating the risk threshold. Actuarial analyses also supported the 25 percent risk threshold. Furthermore, many physicians typically give discounts in the 25 percent range.

The majority of arrangements that exceed the threshold are capitation arrangements, where 100 percent of the income is put at risk. For these arrangements, the precise amount at which we

set the threshold will not make a difference, they will exceed any reasonable risk threshold.

Comment: One commenter pointed out a conflict in the regulatory language. At §422.208(c)(2), the regulation specifies that the M+C organization provides stop-loss protection; while at §422.208(f), it specifies that the M+C organization must assure that all physicians and physician groups have stop-loss protection.

Response: The commenter is correct and we are revising the incorrect language in §422.208(c)(2) to eliminate this discrepancy. We note that paragraph (f) incorporates the language from §417.479 (the physician incentive regulation that applied to section 1876 contracts) that we indicated in the preamble to the physician incentive regulation that we intended to adopt.

Comment: One commenter contended that the physician incentive plan requirements are excessively detailed, prescriptive, and confusing. The commenter argued that the detailed stop-loss insurance requirements impose additional costs on the delivery of health care, costs that are increasingly borne by the physician practices, not M+C organizations. The commenter urged us to monitor the stop-loss insurance market carefully, and provide prior review of panel size, and deductible limits set

forth in the rule to ensure that they are not necessarily restrictive.

Response: In the preamble to the December 31, 1996 final rule (61 FR 69034) containing the section 1876 physician incentive requirements upon which §§422.208 and 422.210 were based, we presented a regulatory impact analysis. In that analysis, we concluded that only a small number of organizations and physician groups would need to increase their stop-loss protections, and that this increase would be small relative to the total amount of income. Furthermore, stop-loss insurance is required by statute where substantial financial risk is imposed, and it provides increased protection to physicians that helps reduce possible incentives to deny necessary care. These requirements have been in place for 3 years, and do not appear to have caused any significant problems for M+C organizations or their predecessors.

Comment: A commenter requested that these rules should apply to Federally Qualified Health Centers (FQHCs) and all associated health care providers. The commenter pointed out that these rules appear limited to individual physicians, physician groups, and intermediate entities acting as subcontractors.

Response: If the FQHC is an intermediate entity, subcontractor, or a physician group as specified in these regulations, then the provisions apply.

Comment: One commenter wanted to know if we review disclosures for both the Medicare and Medicaid programs.

Response: The regulations require that M+C organizations that participate in the M+C program must disclose incentive plan arrangements to us, while managed care organizations that participate in the Medicaid program disclose incentive plan arrangements to the State Medicaid Agencies. We review the monitoring activities of State Medicaid Agencies.

Comment: One commenter indicated support for the methodology for disclosing incentive plans, but requested that we make clear that we do not require the precise formula and payment amounts be disclosed.

Response: Section 422.210(b) requires that an M+C organization must provide the following information to any Medicare beneficiary who requests it: (1) whether the M+C organization uses a physician incentive plan that affects the use of referral services; (2) the type of incentive arrangement; (3) whether stop-loss protection is provided; and (4) if the M+C organization was required to conduct a survey, a summary of the survey results.

As we indicated in guidance provided in December 1996 to section 1876 contractors, M+C organizations do not have to disclose to beneficiaries the precise formula and payment amounts involved, nor do they have to provide incentive plan information

for individual physicians or physician groups. Only summary information needs to be reported. However, the M+C organizations are required to report more detailed information to us or the State Medicaid Agencies.

8. Special Rules for Services Furnished by Noncontract Providers (§422.214)

Consistent with sections 1852(k)(1) and 1866(a)(1)(O) of the Act, §422.214 requires that any health care provider that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an M+C coordinated care plan must accept, as payment in full, the amounts that they could collect if the beneficiary were enrolled in original Medicare (less the amounts specified in §§412.105(g) and 413.86(d) of the regulations on hospital graduate medical education payments, when applicable). Any statutory provisions (including penalty provisions) that apply to payment for services furnished to a beneficiary not enrolled in an M+C plan also apply to the payment described in §422.214(a)(1) of our regulations. We received three comments regarding this section.

Comment: Several commenters suggested that we revise §422.214 to provide that payment to a noncontracting provider must equal the amount that provider would be allowed to collect under original Medicare. These commenters believe that M+C organizations should only be permitted to pay the billed amount

when this is the same amount that Medicare would pay under original Medicare.

Response: Section 422.214 implements section 1866(a)(1)(O) of the Act, with respect to services furnished by a "provider of services" as defined in section 1861(u), and section 1852(k)(1), with respect to other services. Neither of these provisions requires an M+C organization to pay a provider more than the amount of the provider's bill, or even impose obligations on M+C organizations at all. Rather, these provisions serve as a limit on the amount the provider can collect from the M+C organization. Specifically, each of these provisions states that a provider "shall accept as payment in full" the amount (less the amounts specified in §§412.105(g) and 413.86(d) of the regulations) that it would receive under original Medicare, including cost sharing and permitted balance billing ("the Medicare payment amount"). While this means that under these provisions the provider cannot collect more than the Medicare payment amount if its billed amount is higher, this obligation to "accept" the Medicare amount as payment in full does not obligate the M+C organization to pay this amount if the provider's bill is lower. Thus, in the case of emergency services and certain other services referred to in section 1852(d)(1)(C) of the Act furnished to an enrollee in a coordinated care plan, the provider or providers must accept the Medicare payment amount for the services if their billed amount

is higher, but would have no right under sections 1852(k)(1) or 1866(a)(1)(O) to be paid more than the amount of their bill if the billed amount is lower than the Medicare payment amount.

We note, however, that a provision in the BBA does give providers furnishing services to coordinated care plan enrollees the right to be paid the Medicare payment amount under certain circumstances. Section 1852(a)(2) provides that where an M+C organization chooses to furnish services through providers that do not have contracts with the organization in order to meet its obligation under section 1852(a)(1) to make Medicare services available, it must provide for payment "equal to at least" the Medicare payment amount. (Emphasis added.) This new provision, unlike section 1866(a)(1)(O) or section 1852(k)(1), establishes a "floor" for payment when it applies. This "floor," combined with the "ceilings" under sections 1866(a)(1)(O) and 1852(k)(1), essentially requires that the Medicare payment amount be paid where section 1852(a)(2) applies. Because section 1852(a)(2) refers to an M+C organization's furnishing services in fulfillment of its obligations under section 1852(a)(1), we are interpreting section 1852(a)(2), in the coordinated care plan context, as providing M+C organizations with the opportunity to arrange to provide nonemergency services through noncontracting providers. Under this interpretation, the "minimum payment" requirement in section 1852(a)(2) would only apply where the M+C

organization has arranged for the services in question to be provided by a noncontracting provider. In the coordinated care plan context, therefore, payment for emergency services and those services referred to in section 1852(d)(1)(C) would continue to be subject only to the rules in sections 1852(k)(1) and 1866(a)(1)(O). In the private fee-for-service plan context, however, section 1852(k)(2)(B)(i) of the Act provides that all services furnished by noncontracting providers are subject to the "minimum payment rate" in section 1852(a)(2).

To summarize our position, in the case of services arranged by an M+C organization to be furnished by a noncontracting provider to a coordinated care plan enrollee, or any services furnished by a noncontracting provider to a private fee-for-service plan enrollee, section 1852(a)(2) applies, and the M+C organization must pay the Medicare payment amount. In the case of emergency services (referred to in section 1852(d)(1)(E)), urgently needed services (referred to in section 1852(d)(1)(C)(i)), renal dialysis services provided out of the M+C plan’s service area (referred to in section 1852(d)(1)(C)(ii)), and maintenance care or poststabilization services (referred to in section 1852(d)(1)(C)(iii)) furnished to a coordinated care enrollee by a noncontracting provider, the provider is required to accept the Medicare payment amount as

payment in full, but the M+C organization is not required to pay more than the billed amount.

Comment: One commenter suggested that we should clearly lay out the process and requirements for compliance with the provisions of §422.214. In order to implement the payment limits in §422.214 and not overpay noncontracting providers, M+C organizations will have to develop a process that would apply applicable Medicare payment limits to charges for services furnished to enrollees by noncontracting providers. M+C organizations will need detailed information from us describing each of Medicare's payment limits, how each limit is applied, and which limits apply to which provider.

Response: The comment addresses the need for a process to implement the payment limits contained in §422.214. We understand that any process used to apply Medicare payment limits will require a significant amount of data and will be relatively complex. However, we do not feel that the requirements for such a process should be set forth in regulation. Each M+C organization should be allowed to develop a process that will satisfy that organization's needs.

As discussed in further detail in section II.Q of this preamble, we anticipate that the organizations offering M+C private fee-for-service (PFFS) plans may have a particular need for such a process, both to pay non-contracting providers who

must be paid at least the amount they could collect under original Medicare, and to pay contracting and deemed contracting providers, assuming that the M+C organization offering the PFFS plan has chosen to meet access requirements by paying contracting providers "no less than" the amount paid under original Medicare. Therefore, we have decided to permit M+C organizations offering PFFS plans to establish "proxies" for use in paying services for which no Medicare prospective payment system or fee schedule exists, provided that the proxy methodology has been approved by us as not being less than the expected Medicare payment amount.

We emphasize that the proxy methodologies will be designed to provide an accurate estimate of the Medicare payment amount, including possible beneficiary cost-sharing under original Medicare. In some cases (for example, for Medicare-certified hospitals, SNFs, or HHAs, or for Medicare-participating physicians), this is the amount that a noncontracting provider is required to accept as payment in full from the M+C organization. In other cases, the amount that a noncontracting provider may collect is not limited to the Medicare payment amount but could include allowable balance billing amounts under original Medicare. In such a case, the provider has a right to collect more from the M+C organization than the Medicare payment amount reflected in the proxy (and in the case of a non-contracting provider furnishing services to a PFFS plan enrollee, the M+C

organization may have an obligation to pay more than the proxy amount).

Comment: One commenter asked whether the statement in the preamble that "the M+C organization must hold beneficiaries harmless against any such balanced billing" means that an M+C organization must pay billed charges to noncontracting providers regardless of the Medicare fee schedule.

Response: No. Section 422.214 clearly states that a noncontracting provider must accept as payment in full what the provider could collect under original Medicare (less any payments under §§412.105(g) and 413.86(d)). Please note that some providers may be entitled to receive an amount that is in excess of the Medicare fee schedules, but that does not exceed the limiting charge.

9. Exclusion of Services Furnished Under a Private Contract (§422.220)

An M+C organization may not pay, directly or indirectly, on any basis, for services (other than emergency or urgently needed services as defined in §422.2) furnished to a Medicare enrollee by a physician (as defined in section 1861(r)(1) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare carrier an affidavit promising to furnish Medicare-covered services to Medicare beneficiaries only through private contracts with the beneficiary

under section 1802(b) of the Act. An M+C organization must pay for emergency or urgently needed services furnished by a physician or practitioner who has not signed a private contract with the beneficiary.

Comment: One commenter contended that it is difficult to exclude private contracting physicians and practitioners from payment because there is no central list of private contractors. This commenter believes that we should list these physicians and practitioners on our website, and include unique identifiers, like the physician or practitioner's SSN.

Response: We recognize that it is difficult for M+C organizations to acquire timely and accurate information on "opt out" physicians with whom they do not have a contract, and we are working on a way of making this information available to them as soon as possible. M+C organizations offering coordinated care plans could seek this information from the provider or supplier before they authorize the use of a noncontracting physician or practitioner. Moreover, we do not anticipate that the absence of such knowledge would be a problem in cases of emergency or urgent care since in those cases, the services of the opt-out physician or practitioner are covered (unless the enrollee/beneficiary has previously signed a private contract).

As part of our effort to streamline the flow of information on opt-out physicians and practitioners, we are also considering

what information can be placed on a list or made available through a website. Some information such as the SSN cannot be disclosed under the Privacy Act.

Currently, M+C plans should contact the Medicare carrier with jurisdiction over the payment of claims under original Medicare in their service area to work out a mutually agreeable means of receiving this information on a timely basis. Disputes should be referred to the HCFA regional office for resolution.

With respect to contracting physicians, M+C organizations may, through their contracts, require contract providers to notify them immediately when they enter into private contracts under section 1802(b). This will provide the information more timely than any process that might be arranged with Medicare carriers or through a listing prepared by us, and will permit the M+C organization to cease payment immediately to the contracting physician or practitioner who has opted out of Medicare.

Comment: One commenter urged that we monitor the disease type and severity of diseases of beneficiaries who privately contract with physicians to determine what future program changes are appropriate.

Response: We are required by section 4507 of the BBA to provide a report to the Congress by October 1, 2001 on the effect of private contracting and to provide recommendations for

legislation in this regard. We are conducting a broad study of claims data that will be used to prepare that report.

Comment: A commenter suggested that the private fee-for-service plan discussion of deemed and non-contracting providers be revised to indicate that these payment restrictions do not apply if the provider has opted out under §422.220.

Response: We have included a clarification by cross reference.

Comment: A commenter believes that beneficiaries need to be advised in both HCFA and M+C plan information that no payment can be made by the M+C organization for services provided under private contract with a physician who has entered into a contract under section 1802(b).

Response: We agree that it is important that M+C plan enrollees know that no payment can be made under the M+C plan for services of physicians and practitioners who have entered into contracts under section 1802(b). Section 1802(b) and private contracting regulations at §405.400 both require that a private contracting physician or practitioner have the beneficiary (enrollee in the case of M+C plans) sign a private contract that notifies him or her that no Medicare payment will be made for the services of the opt-out physician or practitioner, and that he or she accepts full responsibility for payment of the opt-out physician or practitioner's services (except in cases of

emergency medical condition or urgent care in which the physician or practitioner cannot ask the beneficiary to sign a private contract and Medicare will pay for the care). Hence, the plan enrollee should be specifically aware of the effect of receiving services from an opt-out physician or practitioner before he or she receives these services. We will, however, also consider adding a discussion of private contracting to the model evidence of plan coverage.

10. M+C Plans and the Physician Referral Prohibition

The physician referral prohibition in section 1877 of the Act concerns M+C organizations, although the implementing regulations are located in subpart J of part 411 rather than in part 422. Under section 1877, if a physician or a member of a physician's immediate family has a financial relationship with a health care entity (through an ownership interest or a compensation relationship), the physician may not refer Medicare patients to that entity for any of 11 designated health services, unless an exception applies. Under section 1877(b)(3) of the Act and §411.355(c) of the regulations, services furnished by section 1876 contractors to their enrollees were exempted from the physician referral prohibition. In the June 1998 interim final rule, we revised §411.355(c) to similarly exclude from the physician referral prohibition services furnished under an M+C coordinated care plan to an enrollee. We did not exclude

services furnished by private fee-for-service plans or MSA plans from the physician referral prohibition. Subsequently, section 524 of the BBRA amended section 1877(b)(3) of the Act by adding a new subparagraph (E) to exempt an M+C organization offering an M+C coordinated care plan from the physician referral prohibition. The comments and responses regarding this subject are discussed below.

Comment: One commenter argued that services furnished under an MSA plan or private fee-for-service plan should also be excluded from the physician referral provisions. The commenter believed that while there are differences between these types of plans and coordinated care plans, patients who elect coverage under an MSA plan or a fee-for-service plan do so knowing that their out-of-pocket liabilities are not controlled to the same degree as in a coordinated care plan. In the commenter's view, concerns about beneficiaries should be addressed in the context of disclosures by the M+C organization offering the MSA plan or private fee-for-service plan, prior to enrollment, rather than by the section 1877 provisions. At most, this commenter would require only that M+C organizations offering plans of these types disclose financial interests in entities that furnish designated health services in return for an exception from the prohibition in section 1877.

Response: As we understand the argument, the commenter has suggested that we should exclude M+C private fee-for-service plans and M+C MSA plans from the prohibition on referrals under section 1877 because the concerns addressed by section 1877, that, in general, a physician should not profit from his or her referrals for certain services, has already been accommodated. The commenter believes that beneficiaries already understand that in these plans their out-of-pocket liabilities are not controlled to the same degree as in a coordinated care plan, and that any problems that still might exist can be addressed by more disclosure.

We do not understand why a beneficiary's knowledge of the differences between coordinated care plans and private fee-for-service/MSA plans addresses the concerns behind our decision not to exempt services furnished under the latter plans from the prohibition in section 1877. Under section 1877, we can create a new exception only if the Secretary determines, and specifies in regulations, that a financial relationship between a physician and an entity to which the physician refers does not pose a risk of program or patient abuse. Pursuant to this authority, we exempted services furnished under coordinated care plans because the Congress had already exempted the identical type of arrangement when it exempted services furnished under section 1876 contracts, (and likely inadvertently failed to make a

conforming change to this exception when M+C contracts replaced section 1876 contracts), and because we did not see a potential for program or patient abuse in the case of coordinated care plans. This latter conclusion was based on the facts that, as in the case of a section 1876 risk contractor: (1) a physician working with an M+C organization offering a coordinated care plan has no incentive to order unnecessary care, since physicians are not paid for ordering additional services; (2) the organization has control over its network of providers, and provides incentives for its network providers to avoid unnecessary care; and (3) incentives to deny necessary care are addressed by physician incentive plan requirements limiting the risk that can be imposed on physicians. These are the same physician incentive plan requirements that are incorporated in a section 1877 provision permitting certain risk arrangements that would otherwise be subject to the referral prohibition. (See section 1877(e)(3)(B) of the Act.)

In contrast, under M+C MSA plans or private fee-for-service plans, individual providers, including physicians, are paid on a fee-for-service basis for services provided, and thus have the same kind of incentives to provide unnecessary services that gave rise to the enactment of section 1877. Although this would not result in more Medicare funds being expended during the year in question, it could harm beneficiaries in two ways. First, it

could result in higher cost-sharing paid by beneficiaries in the current year. Second, it could result in the M+C organization offering less in benefits the following year than it would otherwise be able to offer if its expenses were not as high. For these reasons, we do not believe that the exception from the physician referral prohibition that we have created for services furnished under coordinated care plans should apply to services under M+C private fee-for-service plans or MSA plans. We note that the Congress implicitly endorsed our position through the amendments to section 1877 included in section 524 of the BBRA. This section explicitly exempted M+C coordinated care plans from the physician referral prohibitions, but did not include any changes related to other types of plans.